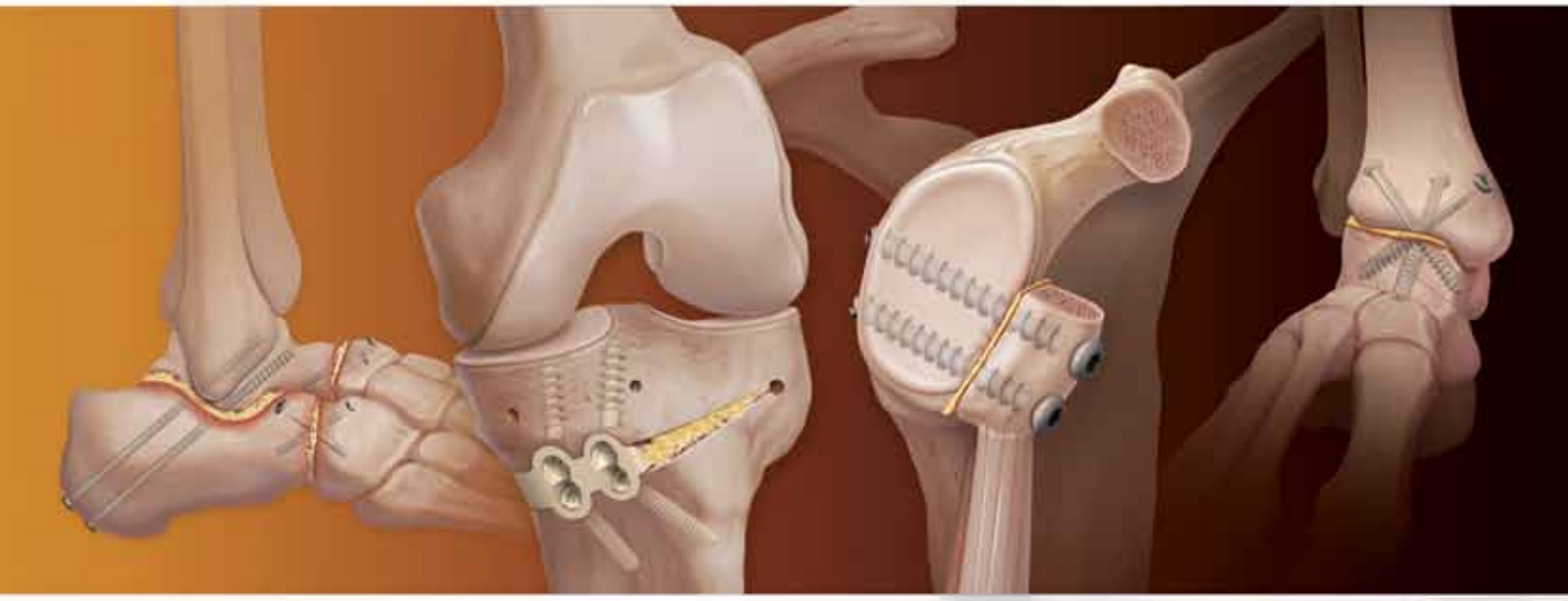
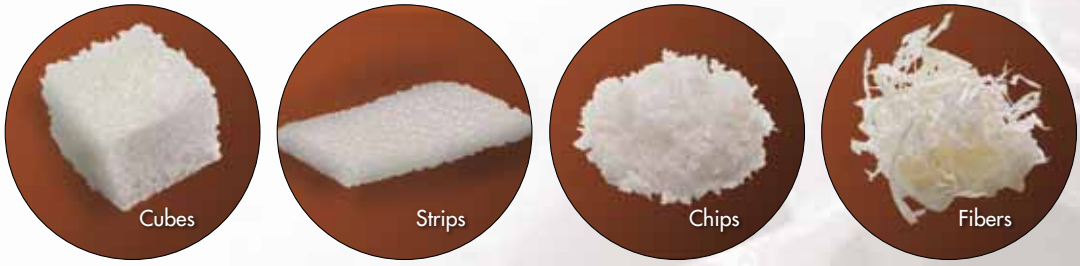
FlexiGRAFT®



Demineralized Cancellous Sponges and Cortical Fibers



LifeNet Health®
Saving Lives, Restoring Health

Arthrex®
ORTHOBIOLOGICS
http://biologics.arthrex.com

FlexiGRAFT® Demineralized Sponge

Features and Benefits:

- Demineralized cancellous matrix comprised of 100% cancellous bone
- Maintains natural bone architecture with interconnected porosity
- Provides optimal scaffold for cellular attachment and proliferation
- Contains exposed natural growth factors with osteoinductive potential
- Naturally absorbs and retains bioactive fluids like platelet rich plasma (PRP) and bone marrow aspirate (BMA)
  - After rehydration, the product is compressible like a sponge, allowing for flexibility to fit in and around different types of bone defects
- Sterile to device grade standards (10^{-6}) and stored at room temperature

Osteoinductivity Testing*

- The FlexiGraft Demineralized Sponge was tested in an intramuscular nude rat bioassay via histological evaluations
- Similar volumes of nondemineralized cancellous and cortical DBM particulate were implanted to serve as negative and positive controls, respectively
- After 28 days, the following findings were observed within the FlexiGraft group (Figure 1):
  - The porous osteoconductive trabecular bone structure of the implant was maintained and found to be evident within the histological sections (black arrow)
  - Osteoblast-like cells were found lining the trabecular bone network (blue arrow)
  - Cellular infiltration and neovascularization was very apparent along the edges of the implant but also could be observed throughout the interior portion of the implant (red arrow)

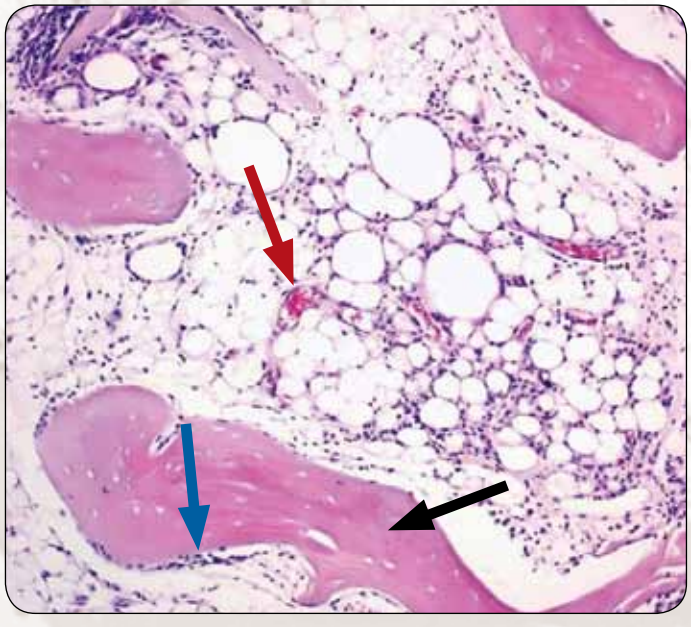
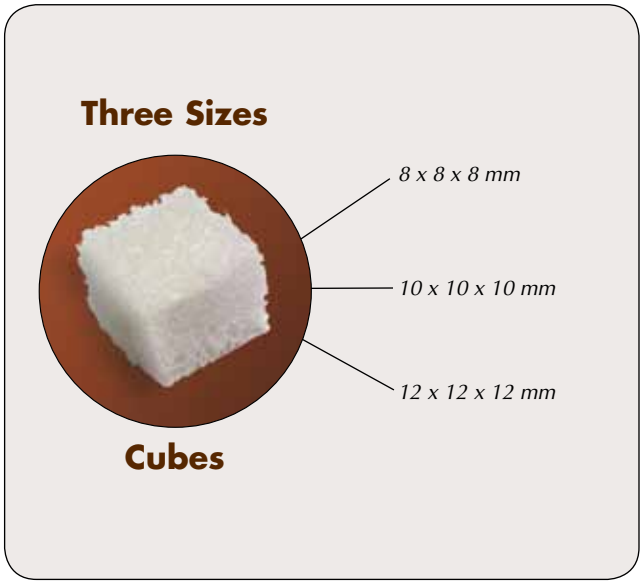
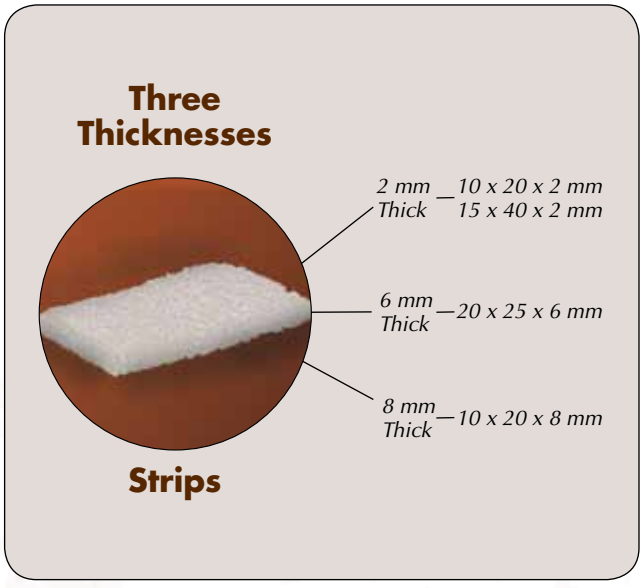
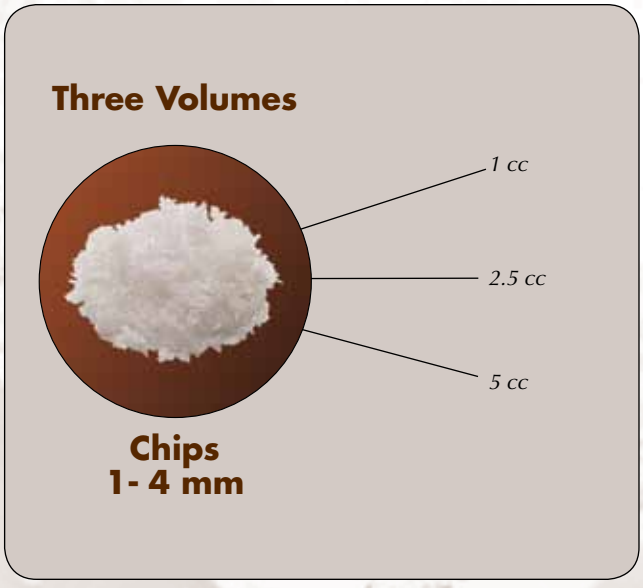


Figure 1: Representative histology of demineralized sponge, H&E stained

**Data on file at LifeNet Health*





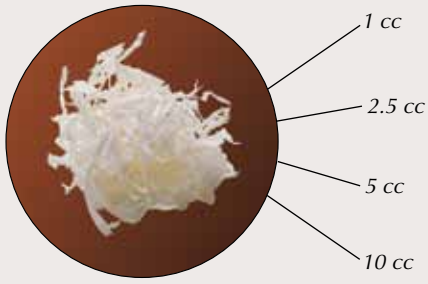


FlexiGRAFT® Demineralized Fibers

Features and Benefits:

- New form of 100% DBM offering excellent handling characteristics without the need for an additional carrier
- Maintained osteoconductive and osteoinductive potential
  - The cortical fibers are demineralized using LifeNet Health's patented and proprietary process-optimizing the residual calcium level and osteoinductive potential
  - Demineralized cortical fibers provide an optimal scaffold for cellular attachment and proliferation
- Customizable hydration: naturally wicks up bioactive fluids such as PRP and BMA
- Sterile to device grade standards (10^{-6}) and stored at room temperature

Four Sizes



Testing of Osteoinductive Potential with a Fusion Model*

- An athymic rat posterolateral fusion model was used within six rats
- The transverse processes of the L4 and L5 vertebral body were exposed and decorticated bilaterally
- Each side was then implanted with 0.2 cc of FlexiGraft Demineralized Fibers and cancellous
- After eight weeks, they were evaluated using histology, radiography, and microCT:
  - **Histology (Figure 2):**
    - An independent laboratory conducted the histological processing; analysis was conducted to assess new bone formation
    - The demineralized fibers proved to be osteoinductive: areas with concentrated amounts of fibers yielded obvious new bone development
  - **Radiography (Figure 3):**
    - A radiograph for each specimen was graded twice and the scores were averaged and rounded down to get a single fusion score per animal
    - The demineralized fibers exhibited a 6/6 fusion frequency; 100% fusion rate
  - **MicroCT (Figure 4):**
    - An independent laboratory conducted the imaging and analysis; with scores being assessed for each side of the fusion independently
    - The demineralized fibers exhibited a 6/6 fusion frequency; 100% fusion rate

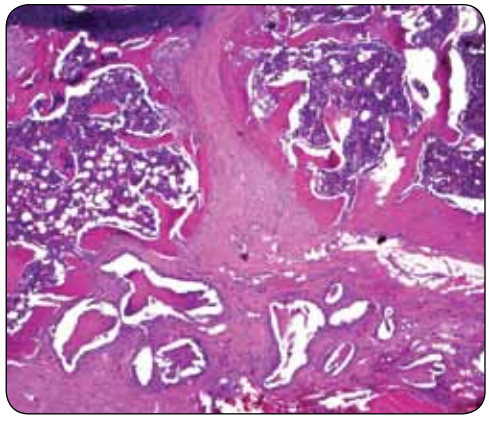


Figure 2: Representative histology of demineralized fibers fusion mass, H&E stained

Figure 3: Representative radiographic image

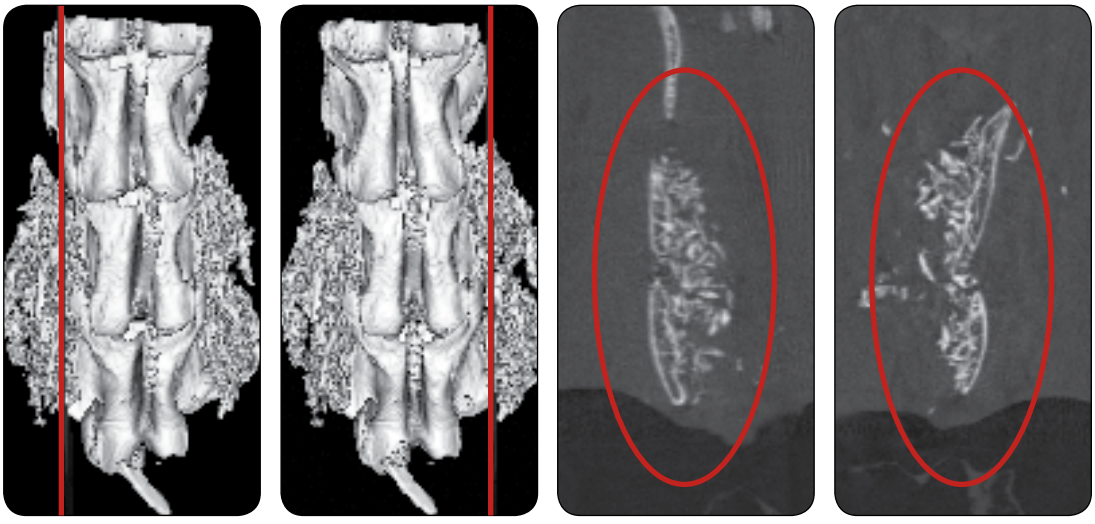


Figure 4: Representative MicroCT images showing bilateral fusion. *Left two images* - the red line indicates the plane of the cross-sectional image. *Right two images* - cross-sectional image of the red line represented on the left two images, the red circle is highlighting the fusion mass.

**Data on file at LifeNet Health*

Combining FlexiGRAFT® with Autologous Products

Allograft demineralized bone is optimal for combination with additional biologically active products. When combined with osteogenic autologous bone marrow and/or autologous platelet-rich plasma, FlexiGraft Demineralized Bone provides the necessary components for bone formation.

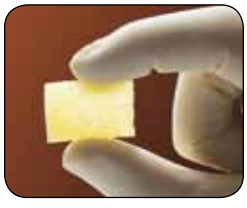
The Bone Marrow Aspiration Kit (AR-1101DS) is a convenient, sterile combination of instruments useful for aspirating the cellular content within bone marrow:

- Bone marrow is a source of autogenous progenitor cells that differentiate into a variety of tissues to include cartilage, tendon, muscle, and nerve, in addition to bone[1-6]
- Bone marrow has been used successfully to augment a number of orthopaedic procedures; including fusions, nonunion grafting, and bridging of osseous defects[7-10]

The Arthrex ACP® (Autologous Conditioned Plasma) Double Syringe (ABS-10010S) can be used for the rapid and efficient concentration of platelets and growth factors within a plasma-based, platelet-rich plasma:

- The unique double syringe design provides a closed system that is easy to use with a quick procedure time
- White and red blood cells are NOT concentrated within the ACP system. Concentrated white blood cells, specifically neutrophils, have been shown to suppress bone formation and bone healing[11-12]
- Leukocyte-reduced, platelet-rich plasma has been found to improve bone regeneration within defect models, for nonunions, and for fusions[13-16]
- For more detailed instructions, follow the Directions for Use outlined in the ACP technique brochure (LB0810)

Strips


Cubes



Chips


Fibers


ACP Basic Preparation

Withdraw venous blood

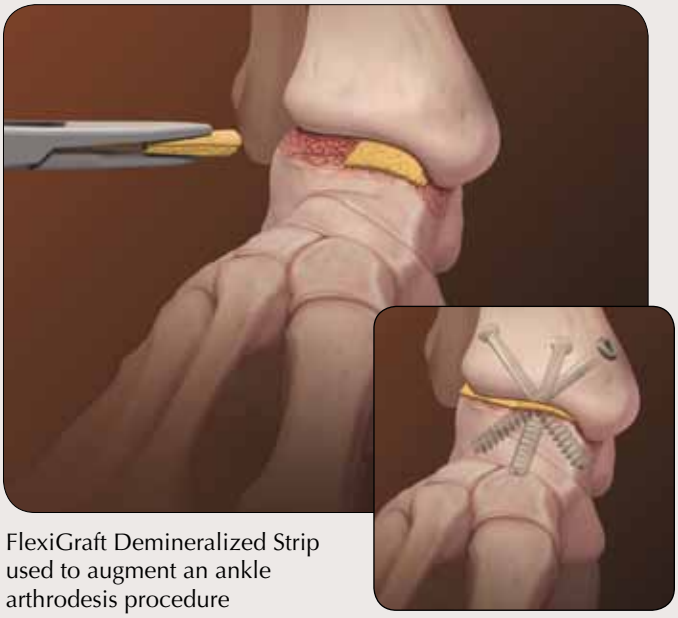
Centrifuge for 5 minutes at 1500 rpm

Transfer 4 - 7 mL of supernatant (ACP) from the outer syringe into the small inner syringe

Bone Marrow Aspiration Kit

ACP Double Syringe

Surgical Applications



FlexiGraft Demineralized Strip used to augment an ankle arthrodesis procedure

FlexiGraft Demineralized Cube used to augment a proximal metatarsal opening wedge procedure

FlexiGraft Demineralized Strip used to augment PIP joint arthrodesis procedures

FlexiGraft Demineralized Fibers used to augment a triple arthrodesis procedure

FlexiGraft Demineralized Strip used to augment a Latarjet procedure

FlexiGraft Demineralized Fibers used to augment an iBalance® HTO procedure

Product Type	Dimensions and Volume	Part Number
	FlexiGraft Demineralized Sponges	
Cube	8 mm x 8 mm x 8 mm	BL-1100-001
Cube	10 mm x 10 mm x 10 mm	BL-1100-003
Cube	12 mm x 12 mm x 12 mm	BL-1100-002
Strip	10 mm x 20 mm x 2 mm	BL-1300-001
Strip	15 mm x 40 mm x 2 mm	BL-1300-002
Strip	20 mm x 25 mm x 6 mm	BL-1300-003
Strip	10 mm x 20 mm x 8 mm	BL-1300-004
Chips (1 - 4 mm)	1.0 cc	BL-1200-001
Chips (1 - 4 mm)	2.5 cc	BL-1200-002
Chips (1 - 4 mm)	5 cc	BL-1200-003
	FlexiGraft Demineralized Fibers	
Fibers	1.0 cc	BL-1000-001
Fibers	2.5 cc	BL-1000-002
Fibers	5 cc	BL-1000-003
Fibers	10 cc	BL-1000-004

To order please call LifeNet Health at 1-888-847-7831.
Contact your local Arthrex Representative for additional information.

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LifeNet Health helps to save lives and restore health for thousands of patients each year. They are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies – a leader in the field of regenerative medicine, while always honoring the donors and health care professionals that allow the healing process.

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U.S. PATENT PENDING

LifeNet Health (68-40-078 Rev. 00)